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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/529,762	04/18/00	RITTERSHAUS	C	TCS-420.1PUS

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EXAMINER	
HUYNH, P	
ART UNIT	**PAPER NUMBER**
1644	3

DATE MAILED: 06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/529,762	RITTERSHAUS ET AL.	
	Examin r	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cov r sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this Action, to elect a single invention to which the claims must be restricted:

I. Claims 1-7, drawn to a vaccine composition comprising a non-endogenous CETP from rabbit CETP, allelic variants and adjuvant effective to promote the production of antibodies.

II. Claims 1-7, drawn to a vaccine composition comprising a non-endogenous CETP from mouse CETP, allelic variants and adjuvant effective to promote the production of antibodies.

III. Claims 1-7, drawn to a vaccine composition comprising a non-endogenous CETP from simian CETP, allelic variants and adjuvant effective to promote the production of antibodies.

IV. Claims 1-7, drawn to a vaccine composition comprising a non-endogenous CETP from humanized rabbit CETP, allelic variants or polymorphs of human CETP and adjuvant effective to promote the production of antibodies.

V. Claims 8-14, drawn to a plasmid-based vaccine comprising a promoter sequence suitable for directing the transcription of a nucleotide sequence in a cell of a mammal operatively linked to a nucleotide sequence coding for a non-endogenous cholesteryl ester transfer protein (CETP) from rabbit CETP and allelic variants.

VI. Claims 8-14, drawn to a plasmid-based vaccine comprising a promoter sequence suitable for directing the transcription of a nucleotide sequence in a cell of a mammal operatively linked to a nucleotide sequence coding for a non-endogenous cholesteryl ester transfer protein (CETP) from mouse CETP and allelic variants.

VII. Claims 8-14, drawn to a plasmid-based vaccine comprising a promoter sequence suitable for directing the transcription of a nucleotide sequence in a cell of a mammal operatively linked to a nucleotide sequence coding for a non-endogenous cholesteryl ester transfer protein (CETP) from humanized rabbit CETP and allelic variants or polymorphs of human CETP.

VIII. Claims 8-14, drawn to a plasmid-based vaccine comprising a promoter sequence suitable for directing the transcription of a nucleotide sequence in a cell of a mammal operatively linked to a nucleotide sequence coding for a non-endogenous cholesteryl ester transfer protein (CETP) from simian CETP and allelic variants.

IX. Claim 15, drawn to a method of promoting production in a mammal of antibodies binding the mammal's endogenous CETP.

X. Claims 16-25, drawn to a method for elevating the ratio of circulating high density lipoprotein-associated cholesterol, decreasing the level of endogenous CETP activity, lowering the of circulating low density lipoprotein-associated cholesterol for treating atherosclerosis in a mammal using rabbit CETP and allelic variants.

XI. Claims 16-25, drawn to a method for elevating the ratio of circulating high density lipoprotein-associated cholesterol, decreasing the level of endogenous CETP activity, lowering the of circulating low density lipoprotein-associated cholesterol for treating atherosclerosis in a mammal using mouse CETP and allelic variants.

XII. Claims 16-25, drawn to a method for elevating the ratio of circulating high density lipoprotein-associated cholesterol, decreasing the level of endogenous CETP activity,

lowering the of circulating low density lipoprotein-associated cholesterol for treating atherosclerosis in a mammal using simian CETP and allelic variants.

XIII. Claims 16-25, drawn to a method for elevating the ratio of circulating high density lipoprotein-associated cholesterol, decreasing the level of endogenous CETP activity, lowering the of circulating low density lipoprotein-associated cholesterol for treating atherosclerosis in a mammal using humanized rabbit CETP and allelic variants or polymorphs of human CETP.

XIV. Claims 26-37, drawn to a method for elevating the ratio of circulating high density lipoprotein-associated cholesterol, decreasing the level of endogenous CETP activity, lowering the of circulating low density lipoprotein-associated cholesterol for treating atherosclerosis in a mammal using a cell transfected with a plasmid coding for rabbit CETP and allelic variants.

XV. Claims 26-37, drawn to a method for elevating the ratio of circulating high density lipoprotein-associated cholesterol, decreasing the level of endogenous CETP activity, lowering the of circulating low density lipoprotein-associated cholesterol for treating atherosclerosis in a mammal using a cell transfected with a plasmid coding for mouse CETP and allelic variants.

XVI. Claims 26-37, drawn to a method for elevating the ratio of circulating high density lipoprotein-associated cholesterol, decreasing the level of endogenous CETP activity, lowering the of circulating low density lipoprotein-associated cholesterol for treating atherosclerosis in a mammal using a cell transfected with a plasmid coding for simian CETP and allelic variants.

XVII. Claims 26-37, drawn to a method for elevating the ratio of circulating high density lipoprotein-associated cholesterol, decreasing the level of endogenous CETP activity, lowering the of circulating low density lipoprotein-associated cholesterol for treating atherosclerosis in a mammal using a cell transfected with a plasmid coding for humanized rabbit CETP and allelic variants or polymorphs of human CETP.

The inventions listed as Groups I-XVII above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Consistent with the International Search Report, the Invention of Group IX (claim 15) was to have no special technical feature that defined the contribution over the prior art of Smith et al (Medical Science Research 21(24): 911-912; PTO 1449).

Smith et al teach a method for promoting the production in a mammal of antibodies binding the mammal's endogenous CETP comprising administering to the mammal a non-endogenous CETP in combination with an adjuvant as recited in claim 15 (See page 911, column 1, Materials and Methods, in particular).

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art, Groups I-XVII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept and therefore lack unity of invention.

4. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
June 28, 2001

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